INTERIM RULEMAKING NOTICE FORM

Proposed Interim Rule Number _____ Rule Number **He-P 4035**

1. Agency Name & Address:
NH Dept. of Health and Human Services
Division of Public Health Services
Radiological Health Section (RHS)
29 Hazen Drive
Concord, NH 03301

5. Filing Date: **July 2, 2015**

2. RSA Authority: **RSA 125-F**
3. Federal Authority: **10 CFR Part 35**
4. Type of Action:
Adoption _____
Amendment _____
Repeal _____
Readoption **X**
Readoption w/amendment _____

6. Short Title: **Use of Radionuclides in the Healing Arts**

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name:	**Catherine Bernhard**	Title:	**Rules Coordinator**
Address:	**Department of Health and Human Services** **Administrative Rules Unit** **129 Pleasant Street** **Concord, NH 03301**	Phone #: Fax#: E-mail:	**271-9374** **271-5590**

TYY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

8. Summary explaining the effect of the rule:

This rule establishes the requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts, and for the issuance of licenses authorizing the medical use of radioactive material which provide for the protection of the public health and safety. Pursuant to RSA 541-A:19, I(d), the proposed interim rule continues the rule without amendment to prevent expiration on August 7, 2015, prior to the completion of updates and revisions needed for the readoption of the rule.

9. Listing of people, enterprises, and government agencies affected by the rule:

This rule affects citizens of New Hampshire, including those who work with radionuclides in the healing arts, and those who receive services medical services from the medical use of radioactive material.

10. Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement.

RULE	STATUTE OR FEDERAL REGULATION IMPLEMENTED
He-P 4035	Section 274 of the AEA of 1954, as amended, and Title 10, Code of Federal Regulations (CFR), Part 35
He-P 4035.01	10 CFR 35.1
He-P 4035.02	10 CFR 35.1
He-P 4035.03	10 CFR 35.2
He-P 4035.04	10 CFR 35.11
He-P 4035.05	10 CFR 35.12, 35.13
He-P 4035.06	10 CFR 35.14
He-P 4035.07	10 CFR 35.20, 35.24
He-P 4035.08	10 CFR 35.21, 35.24
He-P 4035.09	10 CFR 35.22, 35.24
He-P 4035.10	10 CFR 35.24
He-P 4035.11	10 CFR 35.25, 35.27
He-P 4035.12	10 CFR 35.29, 35.80
He-P 4035.13	10 CFR 35.32
He-P 4035.14	10 CFR 35.33, 35.3045
He-P 4035.15	10 CFR 35.49
He-P 4035.16	10 CFR 35.50, 35.60
He-P 4035.17	10 CFR 35.50, 35.60
He-P 4035.18	10 CFR 35.51, 35.61
He-P 4035.19	10 CFR 35.53, 35.63
He-P 4035.20	10 CFR 35.57, 35.65
He-P 4035.21	10 CFR 35.59, 35.67
He-P 4035.22	10 CFR 35.60, 35.69
He-P 4035.23	10 CFR 35.61, 35.69
He-P 4035.24	10 CFR 35.70
He-P 4035.25	10 CFR 35.75
He-P 4035.26	10 CFR 35.80, 35.647
He-P 4035.27	10 CFR 35.90, 35.209
He-P 4035.28	10 CFR 35.92
He-P 4035.29	10 CFR 35.100
He-P 4035.30	10 CFR 35.120
He-P 4035.31	10 CFR 35.200
He-P 4035.32	10 CFR 35.204
He-P 4035.33	10 CFR 35.205
He-P 4035.34	10 CFR 35.220
He-P 4035.35	10 CFR 35.300
He-P 4035.36	10 CFR 35.310
He-P 4035.37	10 CFR 35.320
He-P 4035.38	10 CFR 35.320
He-P 4035.39	10 CFR 35.500

RULE	STATUTE OR FEDERAL REGULATION IMPLEMENTED
He-P 4035.40	10 CFR 35.520
He-P 4035.41	10 CFR 35.400
He-P 4035.42	10 CFR 35.410
He-P 4035.43	10 CFR 35.415
He-P 4035.44	10 CFR 35.406
He-P 4035.45	10 CFR 35.404
He-P 4035.46	10 CFR 35.420
He-P 4035.47	10 CFR 35.600
He-P 4035.48	10 CFR 35.605
He-P 4035.49	10 CFR 35.606
He-P 4035.50	10 CFR 35.610
He-P 4035.51	10 CFR 35.615
He-P 4035.52	10 CFR 35.620

11. Summary of the effect upon the state if the rule were not adopted:

    This interim rule is being submitted pursuant to RSA 541-A:19, I(d) in order to continue the rule which would otherwise expire on August 7, 2015, prior to the completion of updates and revisions necessary for the readoption of the rule. Without these rules, the Department of Health and Human Services/Radiological Health Section will be unable to effectively regulate the safe production, preparation and use of radionuclides in medical research and healing arts facilities, potentially placing the health and safety of the public at risk.

12. Proposed date of review by the Joint Legislative Committee on Administrative Rules: **July 16, 2015.**

13. The fiscal impact statement prepared by the Legislative Budget Assistant.

    There is no requirement for a fiscal impact statement with this interim rule.

Readopt He-P 4035, effective 8/7/07 (Document # 8959), to read as follows:

PART He-P 4035 USE OF RADIONUCLIDES IN THE HEALING ARTS

He-P 4035.01 Purpose. This part shall establish requirements and provisions for the production, preparation, compounding and, use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material which provide for the protection of the public health and safety.

He-P 4035.02 Scope.

(a) The requirements and provisions of this part shall be in addition to, and not in substitution for, other parts in this chapter.

(b) The requirements and provisions of He-P 4019 through He-P 4023, He-P 4030, He-P 4037, He-P 4070, and He-P 4071 apply to applicants and licensees subject to He-P 4035 unless specifically exempted.

He-P 4035.03 Definitions.

(a) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

(b) "Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

(c) "Authorized nuclear pharmacist" means a "licensed pharmacist" as defined in RSA 318:1, VII, who is a qualified nuclear pharmacist under Ph 405.03 and who is identified as an authorized nuclear pharmacist on a DHHS/BRH license that authorizes the use of radioactive material in the practice of nuclear pharmacy.

(d) "Authorized user" means a physician, dentist, or podiatrist, as licensed or permitted by the appropriate state authority, who is identified on a DHHS/BRH license that authorizes the medical use of radioactive material.

(e) "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

(f) "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

(g) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method, and other instructions and precautions, by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

(h) "Management" means the chief executive officer, or equivalent position, or that individual's designee.

(i) "Medical institution" means an organization in which several medical disciplines are practiced.

(j) "Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

(k) "Misadministration" means the administration of:

(1) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131:

a. Involving the wrong patient or human research subject or wrong radiopharmaceutical; or

b. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 megabecquerels (30 μCi);

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

a. Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or

b. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage;

(3) A gamma stereotactic radiosurgery radiation dose:

a. Involving the wrong patient or human research subject or wrong treatment site; or

b. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(4) A teletherapy radiation dose:

a. Involving the wrong patient or human research subject, wrong mode of treatment, or wrong treatment site;

b. When the treatment consists of 3 or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

c. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

d. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(5) A brachytherapy radiation dose:

a. Involving the wrong patient or human research subject, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in

the correct site but migrated outside the treatment site);

b. Involving a sealed source that is leaking;

c. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

d. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose; or

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131, both:

a. Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

b. When the dose to the patient or human research subject exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.

(l) "Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

(m) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(n) "Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

(1) In a written directive; or

(2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(o) "Prescribed dose" means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(3) For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

(p) "Recordable event" means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily

recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and the difference between the administered dosage and the prescribed dosage exceeds 555 kilobecquerels (15 μCi);

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

(q) "Sealed source" means any radioactive material that is enclosed in a capsule designed to prevent leakage or escape of the radioactive material.

(r) "Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an DHHS/BRH license.

(s) "Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

(t) "Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (t)(6) below, containing the following information:

(1) For any administration of quantities greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131: the radionuclide and the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

a. Prior to implantation: the radioisotope, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radioisotope,

treatment site, and total source strength and exposure time (or, equivalently, the total dose).

He-P 4035.04 License Required.

(a) No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to He-P 4030 and He-P 4032.

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in He-P 4035 under the supervision of an authorized user as provided in He-P 4035.11 unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with He-P 4035 under the supervision of an authorized nuclear pharmacist or authorized user as provided in He-P 4035.11 unless prohibited by license condition.

(d) A licensee may conduct research involving human subjects using radioactive material provided that:

(1) The research is conducted, funded, supported, or regulated by a federal agency which has implemented the Federal Policy for the Protection of Human Subjects; or

(2) The licensee has:

a. Applied for and received approval of a specific amendment to its license prior to conducting such research; and

b. Obtained informed consent from the human subjects and has obtained prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

He-P 4035.05 License Amendments. A licensee shall apply for and receive a license amendment:

(a) Before using radioactive material for a method or type of medical use not permitted by the license issued under He-P 4035;

(b) Before permitting anyone to work as an authorized user or an authorized nuclear pharmacist, respectively, under the license;

(c) Before changing a Radiation Safety Officer or Teletherapy Physicist;

(d) Before receiving radioactive material in excess of the amount authorized on the license;

(e) Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

(f) Before changing statements, representations, and procedures which are incorporated into the license.

He-P 4035.06 Notifications. A licensee shall notify the DHHS/BRH in writing within 30 days when an authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or Teletherapy Physicist, permanently discontinues performance of duties under the license.

He-P 4035.07 ALARA Program.

(a) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA).

(b) To satisfy the requirement of He-P 4035.07(a):

(1) The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this chapter, the Radiation Safety Committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

(c) The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or an annual review by management and the Radiation Safety Officer for licensees that are not medical institutions.

(d) The program review required in He-P 4035.07(c) shall include summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material.

(e) The purpose of the review required in He-P 4035.07(c) shall ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(f) The licensee shall retain a current written description of the ALARA program for the duration of the license.

(g) The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with He-P 4020(c)(8) that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

(4) Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

He-P 4035.08 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer who, with the approval of the DHHS/BRH, will be responsible for implementing the radiation safety program.

(b) The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

(c) The Radiation Safety Officer shall:

(1) Investigate overexposure, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposal, misadministration, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

a. Authorizing the purchase of radioactive material;

b. Receiving and opening packages of radioactive material;

c. Storing radioactive material;

d. Keeping an inventory record of radioactive material;

e. Using radioactive material safely;

f. Taking emergency action if control of radioactive material is lost;

g. Performing periodic radiation surveys;

h. Performing checks of survey instruments and other safety equipment;

i. Disposing of radioactive material;

j. Training personnel who work in or frequent areas where radioactive material is used or stored; and

k. Keeping a copy of all records and reports required by the DHHS/BRH, a copy of He-P 4019 through He-P 4023, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations;

(3) For medical use not cited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the DHHS/BRH for licensing action; and

(4) For medical use cited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

He-P 4035.09 Radiation Safety Committee.

(a) Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

(b) The Committee required in He-P 4035.09(a) shall meet the following administrative requirements:

(1) Membership shall consist of at least three individuals, as follows:

a. An authorized user of each type of use permitted by the license;

b. The Radiation Safety Officer;

c. A representative of the nursing service; and

d. A representative of management who is neither an authorized user nor a Radiation Safety Officer.

e. Other members may be included on the Radiation Safety Committee as the licensee deems appropriate;

(2) The Committee shall meet at least once each calendar quarter;

(3) To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative;

(4) The minutes of each Radiation Safety Committee meeting shall include:

a. The date of the meeting;

b. Members present;

c. Members absent;

d. Summary of deliberations and discussions;

e. Recommended actions and the numerical results of all ballots; and

f. Documentation of any reviews required in He-P 4035.07(c) and He-P 4035.09(c); and

(5) The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the DHHS/BRH authorizes its disposition.

(c) To oversee the use of licensed material, the Committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review, on the basis of safety and with regard to the training and experience standards of He-P 4035, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or Teletherapy Physicist

before submitting a license application or request for amendment or renewal and before allowing an authorized user or authorized nuclear pharmacist to work under the license;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the DHHS/BRH for licensing action;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

(8) Establish a table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

He-P 4035.10 Statement of Authorities and Responsibilities.

(a) A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.

He-P 4035.11 Supervision.

(a) A licensee who permits the receipt, possession, production, preparation, compounding, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by He-P 4035.04 shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

(2) Periodically review the supervised individual's use of radioactive material, the records kept to reflect this use, and provide re-instruction as needed;

(3) Require an authorized user to be immediately available to communicate with the

supervised individual; and

(4) Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.

(b) A licensee shall require the supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material under He-P 4035.04 to:

(1) Follow the instructions of the supervising authorized nuclear pharmacist or user;

(2) Follow the written radiation safety and quality management procedures established by the licensee; and

(3) Comply with He-P 4019 through He-P 4023 and the license conditions with respect to the use of radioactive material.

(c) A licensee shall require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

(d) A licensee that supervises an individual shall be responsible for the acts and omissions of the supervised individual.

He-P 4035.12 Mobile Nuclear Medicine Service Administrative Requirements.

(a) The DHHS/BRH shall license mobile nuclear medicine services and or clients of such services, limited to the following services:

(1) Uptake, dilution and excretion;

(2) Imaging and localization;

(3) Sealed sources in diagnosis; and

(4) Certain in-vitro clinical or laboratory testing.

(b) The client of the mobile nuclear medicine service shall be licensed by the DHHS/BRH if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

(c) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.

(d) If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile nuclear medicine service.

(e) A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license to receive and possess that radioactive material.

(f) Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.

(g) A mobile nuclear medicine service shall inform a responsible individual, such as a representative of management or a registered nurse in charge of the patient or the registered nurse in charge of the nursing unit, who is on site at each client's address of use at the time that radiopharmaceuticals are being administered.

He-P 4035.13 Quality Management Program.

(a) Each licensee shall establish and maintain a written quality management program to provide assurance that radioactive material or radiation therefrom will be administered as directed by the authorized user.

(b) The quality management program shall include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive is prepared for:

a. Any teletherapy radiation dose;

b. Any gamma stereotactic radiosurgery radiation dose;

c. Any brachytherapy radiation dose;

d. Any administration of quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131; or

e. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, prior to each administration, the patient or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(c) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(d) A written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the

administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

(e) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive as required by He-P 4035.13(d) would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(f) Each licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of a representative sample of patient or human research subject administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, take modifications to meet the objectives of He-P 4035.13(a); and

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for 3 years.

(g) The licensee shall evaluate and respond to each recordable event, within 30 days after discovery of the recordable event, by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record, in an auditable form, for 3 years, of the relevant facts and what corrective action, if any, was taken.

(h) Each licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in He-P 4035.13(b)(1) in an auditable form, for 3 years after the date of administration.

(i) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

(j) Each applicant for a new license shall submit to the DHHS/BRH a quality management program as part of the application for a license and implement the program upon issuance of the license by the DHHS/BRH.

(k) Each existing licensee, under He-P 4035, shall submit a written certification that a quality management program has been implemented.

(l) Each existing licensee shall retain a copy of the quality management program for review by the DHHS/BRH.

He-P 4035.14 Records, Notifications, and Reports of Misadministrations.

(a) For a misadministration, the licensee shall:

(1) Notify the DHHS/BRH by telephone no later than 24 hours after discovery of the misadministration;

(2) Submit a written report to the DHHS/BRH within 15 days after discovery of the misadministration which:

a. Shall include:

1. The licensee's name;

2. The prescribing physician's name;

3. A brief description of the event;

4. Why the event occurred;

5. The effect on the patient or human research subject;

6. What improvements are needed to prevent recurrence; actions taken to prevent recurrence;

7. Whether the licensee notified the patient or human research subject, or the patient's responsible relative or guardian, and if not, why not; and

8. If the patient or human research subject was notified, what information was provided to the patient or human research subject; and

b. Shall not include the patient's or human research subject's name or other information that could lead to identification of the patient or human research subject;

(3) Notify the referring physician and also notify the patient or human research subject of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or human research subject or that, based on medical judgment, telling the patient or human research subject would be harmful;

(4) Not be required to notify the patient or human research subject without first consulting the referring physician unless the referring physician or patient or human research subject cannot be reached within 24 hours, the licensee shall notify the patient or human research subject as soon as possible thereafter;

(5) Not delay any appropriate medical care for the patient or human research subject, including any necessary remedial care as a result of the misadministration, because of any delay in notification; and

(6) Furnish, within 15 days after discovery of the misadministration, if the patient or human research subject was notified a written report to the patient or human research subject by sending:

a. A copy of the report that was submitted to the DHHS/BRH; or

b. A brief description of both the event and the consequences, as they may affect the patient or human research subject, provided a statement is included that the report submitted to the DHHS/BRH can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for 5 years.

(c) The record required in He-P 4035.14(b) shall contain the names of all individuals involved, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

(d) Aside from the notification requirement, nothing in He-P 4035.14(a) – (c) shall affect any rights or duties of licensees and physicians in relation to each other, patients, or human research subjects, or the patient's or the human research subject's responsible relatives or guardians.

He-P 4035.15 Suppliers. A licensee shall use for medical use only:

(a) Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a license issued pursuant to He-P 4030, and He-P 4032.05, He-P4032.06, or He-P 4032.07 or the equivalent regulations of another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission; and

(b) Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Department of Health and Human Services, Food and Drug Administration (FDA); or

(c) Radiopharmaceuticals compounded from a prescription in accordance with the rules of the New Hampshire Board of Pharmacy; and

(d) Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to He-P 4030, or the equivalent regulations of another Agreement State, a Licensing State, or the NRC.

He-P 4035.16 Quality Control of Diagnostic Equipment.

(a) Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies.

(b) As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the DHHS/BRH.

(c) The licensee shall conduct quality control procedures in accordance with written procedures.

He-P 4035.17 Possession, Use, Calibration, and Check of Dose Calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

(b) In the case where the ionization type dose calibrator required in He-P 4035.17(a) cannot be used effectively to verify the administered activity, the licensee shall use an alternative method.

(c) Any alternative method to the use of a dose calibrator shall be approved by the DHHS/BRH.

(d) Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

(e) Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient of human research subject.

(f) Each licensee shall have written procedures for the use of the instrumentation required in this section.

(g) As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute in ANSI N42.13-2004, or the licensee shall:

(1) At the beginning of each day of use, check each dose calibrator for constancy on a frequently used setting with a dedicated check source of not less than 1.85 megabecquerels (50 μCi) of any photon-emitting radionuclide with a half-life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least 2 sealed calibration sources, traceable to National Institute of Standards and Technology (NIST) or other standards recognized as being equivalent to NIST:

a. Which contain different radionuclides whose activity:

1. The manufacturer has determined within 5 percent of its stated activity; and

2. Is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide; and

b. At least one of which has principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 10 microcuries (370 kilobecquerels) and the highest dosage that will be assayed;

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used; and

(5) Keep a record of the geometry dependence tests required in (g)(4) above for the duration of the use of the dose calibrator.

(h) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(i) A licensee shall also perform checks and tests required by He-P 4035.17(g) following adjustment or repair of the dose calibrator.

(j) A licensee shall retain a record of each check and test required by He-P 4035.17 for 3 years.

(k) The records required by He-P 4035.17(g) shall include:

(1) For He-P 4035.17(g)(1) the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For He-P 4035.17(g)(2) the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the individual who performed the test;

(3) For He-P 4035.17(g)(3) the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the individual who performed the test; and

(4) For He-P 4035.17(g)(4) the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the individual who performed the test.

He-P 4035.18 Calibration and Check of Survey Instruments.

(a) A licensee shall ensure that the survey instruments used to show compliance with He-P 4035 have been calibrated before first use, annually, and following repair.

(b) To satisfy the requirements of He-P 4035.18(a), the licensee shall:

(1) Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate 2 readings separated by at least 50% of scale rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(c) To satisfy the requirements of He-P 4035.18(b), the licensee shall consider a point as calibrated if:

(1) The indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

(2) The indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

(d) A licensee shall check, but shall not be required to record, each survey instrument for proper operation with the dedicated check source before each use.

(e) The licensee shall retain a record of each calibration required in He-P 4035.18(a) for 3 years.

(f) Each calibration record shall include:

(1) A description of the calibration procedure;

(2) A description of the source used;

(3) The certified dose rates from the source;

(4) The rates indicated by the instrument being calibrated;

(5) The correction factors deduced from the calibration data;

(6) The signature of the individual who performed the calibration; and

(7) The date of calibration.

(g) To meet the requirements of He-P 4035.18(a) – (c), the licensee may obtain the services of individuals licensed by the DHHS/BRH, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments.

(h) Records of calibrations which contain information required by He-P 4035.18(e) and (f) shall be maintained by the licensee.

He-P 4035.19 Assay of Radiopharmaceutical Dosages. A licensee shall meet the following requirements for assay of radiopharmaceutical dosages:

(a) Assay, before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 μCi) of a photon-emitting radionuclide;

(b) Assay, before medical use, the activity of each radiopharmaceutical dosage emitting alpha and/or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:

(1) In unit dosage form, for individual patients or human research subjects from a manufacturer or preparer licensed pursuant to He-P 4032.05 or the equivalent requirements of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State; and

(2) From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit dosages have a calibration traceable to a national standard;

(c) Retain a record of the assays or calibrations required by He-P 4035.19(a) and (b) for 3 years; and

(d) The records required in He-P 4035.19(c) shall contain the:

(1) Radiopharmaceutical, or the radionuclide administered;

(2) Patient's or human research subject's name, and identification number if one has been assigned;

(3) Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;

(4) Date and time of the assay or calibration and the date and time of the administration; and

(5) Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program specified in He-P 4035.19(b).

He-P 4035.20 Authorization for Calibration and Reference Sources. Any person authorized by He-P 4035.04 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by persons specifically licensed pursuant to He-P 4032 or equivalent provisions of the U.S. Nuclear Regulatory Commission, Agreement State, or Licensing State and that do not exceed 555 megabecquerels (15 mCi) each;

(b) Any radioactive material with a half-life of 100 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

(c) Any radioactive material with a half-life greater than 100 days in individual amounts not to exceed 7.4 megabecquerels (200 μCi) each; and

(d) Technetium-99m in individual amounts not to exceed 1.85 gigabecquerels (50 mCi).

He-P 4035.21 Requirements for Possession of Sealed Sources and Brachytherapy Sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall:

(1) Follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the DHHS/BRH; and

(2) Maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall assure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed 6 months or at intervals approved by the DHHS/BRH, another Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

(c) To satisfy the leak test requirements of He-P 4035.21(b), the licensee shall assure that:

(1) Leak tests are capable of detecting the presence of 185 becquerels (0.005 μCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 becquerels (0.001 μCi) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the device containing the source is in the "off" position.

(d) A licensee shall retain leak test records for 5 years.

(e) The leak test records shall contain:

(1) The model number;

(2) Serial number, if assigned, of each source tested;

(3) The identity of each source radionuclide;

(4) The estimated activity of each source radionuclide;

(5) The measured activity of each test sample expressed in becquerels (μCi);

(6) A description of the method used to measure each test sample;

(7) The date of the test; and

(8) The signature of the Radiation Safety Officer.

(f) If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of He-P 4023; and
(2) File a report with the DHHS/BRH within 5 days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

(g) A licensee:

(1) Shall not be required to perform a leak test on the following sources:

a. Sources containing only radioactive material with a half life of less than 30 days;

b. Sources containing only radioactive material as a gas;

c. Sources containing 3.7 megabecquerels (100 μCi) or less of beta or photon-emitting material or 370 kilobecquerels (10 μCi) or less of alpha-emitting material;

d. Seeds of iridium-192 encased in nylon ribbon; and

e. Sources stored and not being used; but

(2) Shall test each such source in (g)(1) above for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer.

(h) A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed 3 months.

(i) The licensee shall retain each sealed source inventory record for 5 years.

(j) The sealed source inventory records shall contain:

(1) The model number of each source;

(2) The serial number, if one has been assigned;

(3) The identity of each source radionuclide;

(4) The estimated activity of each source radionuclide;

(5) The location of each source;

(6) The date of the inventory; and

(7) The signature of the Radiation Safety Officer.

(k) A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored.

(l) The survey required in He-P 4035.21(k) shall not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(m) A licensee shall retain a record of each survey required in He-P 4035.21(k) for 3 years.

(n) The record required in He-P 4035.21(m) shall include:

(1) The date of the survey;

(2) A sketch of each area that was surveyed;

(3) The measured dose rate at several points in each area expressed in microsieverts (mrem) per hour;

(4) The model number and serial number of the survey instrument used to make the survey;

and

(5) The signature of the Radiation Safety Officer.

He-P 4035.22 Syringe Shields and Labels.

(a) A licensee shall keep syringes that contain radioactive material to be administered in an appropriate radiation shield or shielded area.

(b) A licensee shall require each individual who prepares or administers radiopharmaceuticals to use an appropriate syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

(c) A licensee shall conspicuously identify each syringe, or syringe radiation shield as to contents or intended patient or human research subject.

He-P 4035.23 Vial Shields and Labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

He-P 4035.24 Surveys for Ambient Radiation Dose Rate and Contamination.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by He-P 4035.25(a) and (b) so as to be able to measure dose rates as low as 1.0 microsievert (0.1 mrem) per hour.

(d) A licensee shall:

(1) Establish dose rate action levels for the surveys required by He-P 4035.24(a) and (b); and

(2) Require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by He-P 4035.24(e) so as to be able to detect contamination as required by He-P 4021.21.

(g) A licensee shall:

(1) Establish removable contamination action levels for the surveys required by He-P

4035.24(e); and

(2) Require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee shall retain a record of each survey required by He-P 4035.24(a)(b) and (e) for 3 years.

(i) The survey record shall include:

(1) The date of the survey;

(2) A sketch of each area surveyed;

(3) Action levels established for each area;

(4) The measured dose rate at several points in each area expressed in microsieverts (mrem) per hour or the removable contamination in each area expressed in becquerels (dpm) per second per 100 square centimeters;

(5) The serial number and the model number of the instrument used to make the survey or analyze the samples; and

(6) The initials of the individual who performed the survey.

He-P 4035.25 Release of Patients or Human Research Subjects Containing Radiopharmaceuticals or Permanent Implants.

(a) A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either:

(1) The dose rate from the patient or human research subject is less than 50 microsieverts (5 mrem) per hour at a distance of one meter; or

(2) The activity in the patient or human research subject is less than 1.11 gigabecquerel (30 mCi).

(b) A licensee shall not authorize release from confinement for medical care any patient or human research subject administered a permanent implant until the dose rate from the patient or human research subject is less than 50 microsieverts (5 mrem) per hour at a distance of 1 meter.

He-P 4035.26 Mobile Nuclear Medicine Service Technical Requirements. A license providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing diagnostic radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each area of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;

(d) In addition to complying with He-P 4035.17 and He-P 4035.18, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use;

(e) Carry a survey meter calibrated in accordance with He-P 4035.18 in each vehicle that is being used to transport radioactive material;

(f) Before leaving a client area of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed;

(g) Retain a record of each survey required by He-P 4035.26(f) for 3 years, including:

(1) The date of the survey;

(2) A plan of each area that was surveyed;

(3) The measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour;

(4) Any removable contamination expressed in becquerels (dpm) per 100 square centimeters;

(5) The model and serial number of the instrument used to make the survey; and

(6) The initials of the individual who performed the survey; and

(h) Use radioactive gases and aerosols only in areas of use and under conditions which have been evaluated and approved by the DHHS/BRH for compliance with airborne release standards.

He-P 4035.27 Storage of Volatiles and Gases.

(a) A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

(b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.

He-P 4035.28 Decay-In-Storage.

(a) A licensee may hold radioactive material for decay-in-storage if the material has a physical half-life of less than 65 days or, if the DHHS/BRH has approved it, material of longer half-life.

(b) Before disposal in ordinary trash, a licensee shall hold radioactive material for decay-in-storage and shall be exempt from the waste disposal requirements of He-P 4023 if the licensee:

(1) Holds radioactive material for decay a minimum of 10 half-lives;

(2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation

level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(c) For radioactive material disposed in accordance with He-P 4035.28(b), the licensee shall retain a record of each disposal for 3 years.

(d) The disposal record shall include:

(1) The date of the disposal;

(2) The date on which the radioactive material was placed in storage;

(3) The model and serial number of the survey instrument used;

(4) The background dose rate;

(5) The radiation dose rate measured at the surface of each waste container; and

(6) The name of the individual who performed the disposal.

He-P 4035.29 Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies. A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion:

(a) Which has been granted acceptance or approval by the U.S. Food and Drug Administration; or

(b) Which is prepared and compounded in accordance with the regulations of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of He-P 4035.64, or an individual supervised by either pursuant to He-P 4035.11.

He-P 4035.30 Possession of Survey Instrument for Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.

(a) A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour.

(b) The instrument in (a) above shall be operable and calibrated in accordance with He-P 4035.18.

He-P 4035.31 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

(a) A licensee may use any radioactive material in a diagnostic radiopharmaceutical (except aerosol or gaseous forms) or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material:

(1) Which has been granted acceptance or approval by the Food and Drug Administration; or

(2) Which has been prepared and compounded in accordance with the regulations of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of He-P 4035.64 or an individual supervised by either pursuant to He-P 4035.11.

(b) A licensee shall elute generators in compliance with He-P 4035.32.

(c) Provided the conditions of He-P 4035.33 are met, a licensee may use radioactive aerosols or gases if specific application is made to and approved by the DHHS/BRH.

He-P 4035.32 Radionuclide Contaminants.

(a) A licensee shall not administer to humans a radiopharmaceutical containing:

(1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);

(2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride); or

(3) More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

(b) A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in He-P 4035.32(a).

(c) A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement for 3 years.

(d) The record required in He-P 4035.32(c) shall include for each elution or extraction tested:

(1) The measured activity of the radiopharmaceutical expressed in megabecquerels or millicuries (mCi);

(2) The measured activity of contaminant expressed in kilobecquerels or microcuries (μCi);

(3) The ratio of the measures expressed as kilobecquerels (μCi) contaminant per megabecquerel (mCi) radiopharmaceutical;

(4) The date of the test; and

(5) The initials of the individual who performed the test.

(e) A licensee shall report immediately to the DHHS/BRH each occurrence of radionuclide contaminant concentration exceeding the limits specified in He-P 4035.32(a).

He-P 4035.33 Control of Aerosols and Gases.

(a) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in He-P 4020.05 and He-P 4020.13.

(b) The system in (a) above shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(c) A licensee shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.

(d) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in He-P 4020.05.

(e) The calculation required in He-P 4035.33(d) shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(f) A licensee shall post the time calculated in He-P 4035.33(d) and (e) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(g) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months.

(h) Records of the checks and measurements required in He-P 4035.33(g) shall be maintained for 3 years.

(i) A copy of the calculations required in He-P 4035.33(d) and (e) shall be recorded and retained for the duration of the license.

He-P 4035.34 Possession of Survey Instruments for Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

(a) A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1,000 mrems) per hour.

(b) The instruments required in He-P 4035.34(a) shall be operable and calibrated in accordance with He-P 4035.18.

He-P 4035.35 Use of Radiopharmaceuticals for Therapy. A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use:

(a) Which has been granted acceptance or approval by the FDA; or

(b) Which has been prepared and compounded in accordance with the rules of the state Board of Pharmacy by an authorized nuclear pharmacist, an authorized user physician who meets the requirements of He-P 4035.64, or an individual supervised by either pursuant to He-P 4035.11.

He-P 4035.36 Safety Instruction for Use of Radiopharmaceuticals for Therapy.

(a) A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy.

(b) Refresher training shall be provided at intervals not to exceed 1 year.

(c) To satisfy the requirements of He-P 4035.36(a), the instruction shall describe the licensee's procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the Radiation Safety Officer or authorized user in case of the patient's or human research subject's death or medical emergency; and

(6) Training for workers as required by He-P 4019.

(d) A licensee shall keep a record of:

(1) Individuals receiving instruction required by He-P 4035.36(a);

(2) A description of the instruction;

(3) The date of instruction; and

(4) The name of the individual who gave the instruction.

(e) The record required in He-P 4035.36(d) shall be maintained for inspection by the DHHS/BRH for 3 years.

He-P 4035.37 Safety Precautions for Use of Radiopharmaceuticals for Therapy.

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with He-P 4035.25, a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous

restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of He-P 4020, He-P 4021, and He-P 4022 and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument to ensure that the removable contamination is less than 3.33 becquerels (200 dpm) per 100 square centimeters before assigning another patient or human research subject to the room;

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of Iodine-131 within 3 days after administering the dosage; and

(9) Retain for the period required by He-P 4021.07 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) For each non-hospitalized patient or human research subject receiving radiopharmaceutical therapy, the licensee shall instruct the patient or human research subject and, where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.

(c) The Radiation Safety Officer or the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

He-P 4035.38 Possession of Survey Instruments for Use of Radiopharmaceuticals for Therapy.

(a) A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsievert (100 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1,000 mrems) per hour.

(b) The survey instruments shall be operable and calibrated in accordance with He-P 4035.18.

He-P 4035.39 Use of Sealed Sources for Diagnosis. A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Iodine-125 as a sealed source in a device for bone mineral analysis;

(b) Americium-241 as a sealed source in a device for bone mineral analysis;

(c) Gadolinium-153 as a sealed source in a device for bone mineral analysis or in a portable device for imaging; and

(d) Iodine-125 as a sealed source in a portable device for imaging.

He-P 4035.40 Availability of Survey Instruments for Use of Sealed Sources for Diagnosis.

(a) A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1,000 mrems) per hour.

(b) The survey instrument shall be operable and calibrated in accordance with He-P 4035.18.

He-P 4035.41 Use of Sources for Brachytherapy. A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

(e) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(f) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(g) Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

He-P 4035.42 Safety Instruction for Use of Brachytherapy Sources.

(a) The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient or human research subject receiving implant therapy.

(b) Refresher training shall be provided at intervals not to exceed one year.

(c) To satisfy He-P 4035.42(a), the instruction shall describe:

(1) The size and appearance of the brachytherapy sources;

(2) The safe handling and shielding instructions in case of a dislodged source;

(3) The procedures for patient or human research subject control;

(4) The procedures for visitor control;

(5) The procedures for notification of the Radiation Safety Officer or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) The training for workers as required by He-P 4019.

(d) A licensee shall maintain a record of individuals receiving instruction required by He-P 4035.42(a), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.

He-P 4035.43 Safety Precautions for Use of Brachytherapy Sources.

(a) For each patient or human research subject receiving implant therapy, a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the radiation dose limits for individual members of the public as specified in He-P 4020.13 at a distance of one meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with He-P 4020, He-P 4021, and He P 4022.

(5) Retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(6) Before authorizing the release of a patient or human research subject administered a permanent implant, instruct the patient or human research subject, and where appropriate, the patient's or human research subject's family, orally and in writing concerning radiation safety precautions that will help keep the radiation dose to household members and the public as low as reasonably achievable.

(b) The Radiation Safety Officer or authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

He-P 4035.44 Brachytherapy Sources Inventory.

(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use or patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use or patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced.

(d) The licensee shall make a record of each survey.

(e) A licensee shall maintain the records required in He P-4035.44(b) and (d) for 3 years.

He-P 4035.45 Release of Patients or Human Research Subjects Treated with Temporary Implants.

(a) Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(b) The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

(c) A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with He-P 4035.45(a) for 3 years, including the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as microsieverts (mrems) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

He-P 4035.46 Possession of Survey Instruments for Use of Brachytherapy Sources.

(a) A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1,000 mrems) per hour.

(b) The instruments shall be operable and calibrated in accordance with He-P 4035.18.

He-P 4035.47 Use of a Sealed Source in a Teletherapy Unit. A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

He-P 4035.48 Maintenance and Repair Restrictions for Sealed Source Teletherapy. Only a person specifically licensed by the DHHS/BRH, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

He-P 4035.49 Amendments for Use of a Sealed Source in Teletherapy. In addition to the requirements specified in He-P 4035.05, a licensee shall apply for and receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

He-P 4035.50 Safety Instruction for Sealed Source Teletherapy.

(a) A licensee shall post written instructions at the teletherapy unit console.

(b) The instructions required in He-P 4035.50(a) shall inform the operator of:

(1) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and

(3) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(c) A licensee shall provide instruction in the topics identified in He-P 4035.50(a) to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

(d) A licensee shall maintain a record of individuals receiving instruction required by He-P 4035.50(c), a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.

He-P 4035.51 Safety Precautions for Sealed Source Teletherapy.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(d) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(e) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source.

(f) The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

(g) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit.

(h) A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(i) A licensee shall retain for 3 years a record of the check required He-P 4035.51(h) including the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

(j) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism.

(k) The radiation monitoring instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use.

(l) The licensee shall keep a record of the instrument checks as described in He-P 4035.51(i).

(m) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(n) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

He-P 4035.52 Possession of Survey Instrument for Use of Sealed Source Teletherapy.

(a) A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 1,000 microsieverts (100 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1,000 mrems) per hour.

(b) The survey instruments shall be operable and calibrated in accordance with He-P 4035.18.

He-P 4035.53 Dosimetry Equipment for Sealed Source Teletherapy.

(a) A licensee shall have a calibrated dosimetry system available for use.

(b) To satisfy the requirement in He-P 4035.53(a), one of the following two conditions shall be met:

(1) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

(2) The system shall have been calibrated within the previous 4 years and 18 to 30 months after the calibration, intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine.

(c) The intercomparison meeting required in He-P 4035.53(b)(2) shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

(d) The results of a calibration intercomparison meeting shall have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent.

(e) The licensee shall not use an intercomparison result to change the calibration factor.

(f) When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source.

(g) When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(h) The licensee shall have available a dosimetry system for spot-check measurements.

(i) The system required in He-P 4035.53(g) may be compared with a system that has been calibrated in accordance with He-P 4035.53(a) through (g) which shall:

(1) Have been performed within the previous year and after each servicing that may have affected system calibration; and

(2) Be the same system used to meet the requirement in He-P 4035.53 (a) through (g).

(j) The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license.

(k) For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by He-P 4035.53(a) through (i), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

He-P 4035.54 Full Calibration Measurements for Use of Sealed Source Teletherapy.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit as follows:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

a. Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of He-P 4035.54(a), full calibration measurements shall include determination of:

(1) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam-localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy;

(5) "On-off" error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in He-P 4035.53 to measure the output for one set of exposure conditions, and the remaining radiation measurements required in He-P 4035.54(b) shall then be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by He-P 4035.54(a) in accordance with the measurements required for annual calibration by "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Medical Physics, Vol. 21, No. 4, 1994, pp. 581-618.

(e) A licensee shall correct mathematically the outputs determined in He-P 4035.54(b) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding 6 months for cesium-137.

(f) Full calibration measurements required by He-P 4035.54(a) and physical decay corrections required by He-P 4035.54(e) shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the NRC or an Agreement State to perform such services.

(g) A licensee shall maintain a record of each calibration for the duration of the license.

(h) The record in (g) above shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

He-P 4035.55 Periodic Spot-Checks for Use of Sealed Source Teletherapy.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at intervals not to exceed one month.

(b) To satisfy the requirement of He-P 4035.55(a), spot-checks shall include determination of:

(1) Timer constancy and timer linearity over the range of use;

(2) "On-off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam-localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for 1 typical set of operating conditions; and

(6) The difference between the measurement made in He-P 4035.55(b)(5) and the anticipated output, expressed as a percentage of the anticipated output (*i.e.*, the value obtained at last full calibration corrected mathematically for physical decay).

(c) A licensee shall perform spot-checks required by He-P 4035.55(a) in accordance with procedures established by the teletherapy physicist.

(d) A licensee shall have the teletherapy physicist review the results of each output spot-check within 15 days.

(e) The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot-check.

(f) The licensee shall keep a copy of each written notification for 3 years.

(g) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility at intervals not to exceed one month.

(h) To satisfy the requirement of He-P 4035.55(g), safety spot-checks shall assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

(i) A licensee shall lock the control console in the "off" position if any door interlock malfunctions until the interlock system is repaired or unless use is specifically authorized by the DHHS/BRH.

(j) A licensee shall not use and shall promptly repair any system identified in He-P 4035.55(h) that is not operating properly.

(k) A licensee shall maintain a record of each spot-check required by He-P 4035.55(a) and (g) for 3 years.

(l) The record shall include:

(1) The date of the spot-check;

(2) The manufacturer's name, model number, and serial number for both the teletherapy unit and source;

(3) The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit;

(4) The measured timer accuracy;

(5) The calculated "on-off" error;

(6) A determination of the coincidence of the radiation field and the field indicated by the light beam-localizing device;

(7) The measured timer accuracy for a typical treatment time;

(8) The calculated "on-off" error, the estimated accuracy of each distance measuring or localization device;

(9) The difference between the anticipated output and the measured output;

(10) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors; and

(11) The signature of the individual who performed the periodic spot-check.

He-P 4035.56 Radiation Surveys for Teletherapy Facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by He-P 4035.49, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with He-P 4035.18 to verify that:

(1) The maximum and average radiation levels at one meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 100 microsieverts (10 mrems) per hour and 20 microsieverts (2 mrems) per hour, respectively; and

(2) With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in He-P 4020.05; and

b. Radiation levels in unrestricted areas do not exceed the limits specified in He-P 4020.13.

(b) If the results of the surveys required in He-P 4035.56(a) indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(2) Until the licensee has received a specific exemption from the DHHS/BRH.

(c) A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license.

(d) The record required in He-P 4035.56(c) shall include:

(1) The date of the measurements;

(2) The reason the survey is required;

(3) The manufacturer's name, model number and serial number of the teletherapy unit;

(4) The source, and the instrument used to measure radiation levels;

(5) Each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements;

(6) A plan of the areas surrounding the treatment room that were surveyed;

(7) The measured dose rate at several points in each area expressed in microsieverts (mrems) per hour;

(8) The calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and

(9) The signature of the Radiation Safety Officer.

He-P 4035.57 Safety Spot-Checks for Teletherapy Facilities.

(a) A licensee shall promptly spot-check all systems listed in He P 4035.55(h) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by He- P 4035.49.

(b) If the results of the spot-checks required in He-P 4035.57(a) indicate the malfunction of any system specified in He-P 4035.55, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall maintain a record of the facility checks following installation of a source for 3 years.

(d) The record required in He-P 4035.57(c) shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.

He-P 4035.58 Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by He-P 4035.56 indicates that an individual in an unrestricted area may

be exposed to levels of radiation greater than those permitted by He-P 4020.13, before beginning the treatment program the licensee shall:

(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with He-P 4020.13;

(b) Perform the survey required by He-P 4035.56 again; and

(c) Include in the report required by He-P 4035.59 the results of the initial survey, a description of the modification made to comply with He-P 4035.58(a) and the results of the second survey; or

(d) Request and receive a license amendment under He P 4020.13(c) and (d) that authorizes radiation levels in unrestricted areas greater than those permitted by He-P 4020.13(a).

He-P 4035.59 Reports of Teletherapy Surveys, Checks, Tests and Measurements. A licensee shall furnish a copy of the records required in He-P 4035.56, He-P 4035.57, and He-P 4035.58, and the output from the teletherapy source expressed as grays (rads) per hour at one meter from the source and determined during the full calibration required in He-P 4035.54, to the DHHS/BRH within 30 days following completion of the action that initiated the record requirement.

He-P 4035.60 Five Year Inspection of Teletherapy Units.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing shall only be performed by persons specifically licensed to do so by the DHHS/BRH, an Agreement State, or the U.S. Nuclear Regulatory Commission.

(c) A licensee shall maintain a record of the inspection and servicing for the duration of the license.

(d) The record required in He-P 4035.60(c) shall contain:

(1) The inspector's name;

(2) The inspector's license number;

(3) The date of inspection;

(4) The manufacturer's name and model number and serial number for both the teletherapy unit and source;

(5) A list of components inspected;

(6) A list of components serviced and the type of service;

(7) A list of components replaced; and

(8) The signature of the inspector.

He-P 4035.61 Radiation Safety Officer Training. Except as provided in He-P 4035.62, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in He-P 4035.08 shall:

(a) Be certified by the:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) The American Board of Medical Physicists in Radiation Oncology Physics;

(6) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(7) Royal College of Physicians and Surgeons of Canada in Nuclear Medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine;

(b) Meet the following requirements:

(1) Have had 200 hours of classroom and laboratory training covering:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity;

d. Radiation biology; and

e. Radiopharmaceutical chemistry; and

(2) Have had one year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an DHHS/BRH, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

(c) Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.

He-P 4035.62 Training for Experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on an DHHS/BRH, Agreement State, Licensing State, or U.S. Nuclear Regulatory Commission license on October 1, 1986 who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of He-P 4035.61.

He-P 4035.63 Training for Uptake, Dilution, or Excretion Studies.

(a) Except as provided in He-P 4035.71 and He-P 4035.72, the licensee shall require the authorized user of a radiopharmaceutical listed in He-P 4035.29 to be a physician who:

(1) Is certified in:

a. Nuclear medicine by the American Board of Nuclear Medicine;

b. Diagnostic radiology by the American Board of Radiology;

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

d. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

e. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience as follows:

a. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiopharmaceutical chemistry; and

b. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients or human research subjects and using syringe radiation shields;

4. Collaborating with the authorized user in the interpretation of radionuclide test

results; and

5. Patient or human research subject follow-up; or

(3) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in He-P 4035.63(a)(2).

(b) Classroom and laboratory training in all the topics identified in He-P 4035.63(a)(2)a., which is not part of a residency program as in He-P 4035.63(a)(3), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience described in He-P 4035.63(a)(2)b. shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures.

He-P 4035.64 Training for Imaging and Localization Studies.

(a) Except as provided in He-P 4035.71 and He-P 4035.72, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in He-P 4035.32 to be a physician who:

(1) Is certified in:

a. Nuclear medicine by the American Board of Nuclear Medicine;

b. Diagnostic radiology by the American Board of Radiology;

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

d. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

e. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience, as follows:

a. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiopharmaceutical chemistry; and

5 Radiation biology;

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

3. Calculating and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent the misadministration of radioactive material;

5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

c. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients or human research subjects and using syringe radiation shields;

4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient or human research subject follow-up; or

(3) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and

supervised clinical experience in all the topics identified in He-P 4035.64(a)(2).

(b) Classroom and laboratory training in all the topics identified in He-P 4035.64(a)(2)a., which is not part of a residency program as in He-P 4035.64(a)(3), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience described in He-P 4035.64(a)(2)b. shall be supervised by a physician licensed for the full scope of diagnostic nuclear medicine procedures.

(d) The experience in He-P 4035.64(a)(2)a. and (a)(2)b. may be obtained concurrently.

He-P 4035.65 Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in He-P 4035.71, the licensee shall require the authorized user of a radiopharmaceutical listed in He-P 4035.36 for therapy to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by The American Board of Nuclear Medicine;

(2) Radiation oncology, therapeutic radiology, or radiology by The American Board of Radiology;

(3) Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(b) Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience, as follows:

(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

a. Radiation physics and instrumentation;

b. Radiation protection;

c. Mathematics pertaining to the use and measurement of radioactivity; and

d. Radiation biology; and

(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

a. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

b. Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

c. Use of iodine-131 for treatment of thyroid carcinoma in three individuals;

d. Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals; and

e. Use of strontium-89 as strontium chloride for the treatment of pain associated with bone metastases in 3 individuals; or

(c) Has successfully completed a 6-month training program in nuclear medicine as part of a residency program that has been approved by the Accreditation Council for Graduate Medical Education (ACGME) which included classroom and laboratory training, work experience and supervised clinical experience and supervised clinical experience in all the topics identified in He-P 4035.65(b).

He-P 4035.66 Training for Therapeutic Use of Brachytherapy Sources.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user using a brachytherapy source specified in He-P 4035.41 for therapy to be a physician who:

(1) Is certified in:

a. Radiology or therapeutic radiology by the American Board of Radiology;
b. Radiation oncology by the American Osteopathic Board of Radiology;

c. Radiology, with a specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience, as follows:

a. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology;

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall

include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;

3. Preparing, implanting, and removing sealed sources;

4. Using administrative controls to prevent the misadministration of radioactive material; and

5. Using emergency procedures to control radioactive material;

c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution; and

d. The supervised clinical experience in (2)c. above shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

2. Selecting the proper brachytherapy sources, dose, and method of administration;

3. Calculating the dose; and

4 Post-administration follow-up and review of case histories in collaboration with the authorized user.

(b) Classroom and laboratory training in all the topics identified in He-P 4035.66(a)(2)a., which is not part of a residency program as in He-P 4035.66(c), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience described in He-P 4035.66(a)(2)b. shall be supervised by a physician licensed for the full scope of therapeutic nuclear medicine procedures.

He-P 4035.67 Training for Ophthalmic Use of Strontium-90.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

(1) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or

(2) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy, as follows:

a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

b. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of 5 individuals that includes:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow-up and review of each individual's case history.

(b) Classroom and laboratory training in all the topics identified in He-P 4035.67(a)(2)a., shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME).

(c) The clinical experience described in He-P 4035.67(a)(2)b. shall be supervised by a physician licensed for the use of sealed sources in therapy.

He-P 4035.68 Training for Use of Sealed Sources for Diagnosis.

(a) Except as provided in He-P 4035.71 the licensee shall require the authorized user using a sealed source in a device specified in He-P 4035.39 to be a physician, dentist, or podiatrist who:

(1) Is certified in:

a. Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology;

b. Nuclear medicine by the American Board of Nuclear Medicine;

c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(2) Has completed 8 hours of instruction in basic radionuclide handling techniques specifically applicable to the use of the device, including training in:

a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

b. Radiation biology; and

c. Radiation protection and training in the use of the device for the purposes authorized by the license.

(b) Classroom and laboratory training in all the topics identified in He-P 4035.68(a)(2), shall:

(1) Be obtained in a medical teaching institution; or

(2) Be approved by the Accreditation Council for Continuing Medical Education (ACCME) or the committee on Postdoctoral training of the American Osteopathic Association (CPTAOA).

(c) The clinical experience shall be supervised by a physician, dentist, or podiatrist licensed to use the devices.

He-P 4035.69 Training for Teletherapy.

(a) Except as provided in He-P 4035.71, the licensee shall require the authorized user of a sealed source specified in He-P 4035.47 in a teletherapy unit to be a physician who:

(1) Is certified in:

a. Radiology or therapeutic radiology by the American Board of Radiology;

b. Radiation oncology by the American Osteopathic Board of Radiology;

c. Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or

d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience, as follows:

a. To satisfy the requirement for instruction, the classroom and laboratory training

shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology;

b. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

1. Review of the full calibration measurements and periodic spot checks;

2. Preparing treatment plans and calculating treatment times;

3. Using administrative controls to prevent misadministrations;

4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

5. Checking and using survey meters;

c. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution; and

d. The supervised clinical experience in (2)c. above shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

2. Selecting the proper dose and how it is to be administered;

3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

4. Post-administration follow-up and review of case histories.

(b) The classroom and laboratory training in all the topics identified in He-P 4035.69(a)(2)a. shall:

(1) Be approved by the Accreditation Council for Continuing Medical Education (ACCME; or

(2) Be approved by the Committee on Postdoctoral Training of the American Osteopathic Association (CPTAOA).

(c) The supervised work and clinical experience described in He-P 4035.69(a)(2)b. and (a)(2)c. and d., respectively, shall be supervised by a physician licensed for teletherapy procedures.

(d) The experience in He-P 4035.69(a)(2)b. – c. may be obtained concurrently.

He-P 4035.70 Training for Teletherapy Physicist.

(a) The licensee shall require the teletherapy physicist to:

(1) Be certified by the American Board of Radiology in:

a. Therapeutic radiological physics;

b. Roentgen-ray and gamma-ray physics;

c. X-ray and radium physics; or

d. Radiological physics;

(2) Be certified by the American Board of Medical Physics in radiation oncology physics; or

(3) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution.

(b) To meet the requirement in He-P 4035.70(a)(3), the individual shall have performed the tasks listed in He-P 4035.21, He-P 4035.54, and He-P 4035.56 under the supervision of a teletherapy physicist during the year of work experience.

He-P 4035.71 Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an DHHS/BRH, NRC, Agreement State, or Licensing State license on April 1, 1997 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of He-P 4035.61 through He-P 4035.73.

He-P 4035.72 Physician Training in a Three-Month Program. A physician who, before July 1, 1984, began a 3-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, shall be exempt from the requirements of He-P 4035.63 or He-P 4035.64.

He-P 4035.73 Recentness of Training. The training and experience specified in He-P 4035.61 through He-P 4035.70 shall have been obtained within the 7 years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

He-P 4035.74 Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a licensed pharmacist, as defined in RSA 318:1, VII, who:

(a) Has current board certification as nuclear pharmacist by the Board of Pharmaceutical Specialties; or

(b) Has met the following requirements:

(1) Has completed 700 hours in a structured educational program consisting of both:

a. Didactic training in the following areas:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Chemistry of radioactive material for medical use; and

5. Radiation biology; and

b. Supervised experience in a nuclear pharmacy involving the following:

1. Shipping, receiving, and performing related radiation surveys;

2. Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

3 Calculating, assaying, and safely preparing dosages for patients or human research subjects;

4 Using administrative controls to avoid mistakes in the administration of radioactive material;

5. Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the training in (b)(1) has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

He-P 4035.75 Training for Experienced Nuclear Pharmacist.

(a) A licensee may apply for and shall receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist.

(b) A pharmacist who has completed a structured educational program as specified in He-P 4035.74(b) before December 2, 1994, and who is working in a nuclear pharmacy shall qualify as an experienced nuclear pharmacist.

(c) An experienced nuclear pharmacist shall not need to comply with the requirements on preceptor statement of He-P 4035.74(b)(2) and recentness of training in He-P 4035.73.

APPENDIX

RULE	STATUTE OR FEDERAL REGULATION IMPLEMENTED
He-P 4035	Section 274 of the AEA of 1954, as amended, and Title 10, Code of Federal Regulations (CFR), Part 35
He-P 4035.01	10 CFR 35.1
He-P 4035.02	10 CFR 35.1
He-P 4035.03	10 CFR 35.2
He-P 4035.04	10 CFR 35.11
He-P 4035.05	10 CFR 35.12, 35.13
He-P 4035.06	10 CFR 35.14
He-P 4035.07	10 CFR 35.20, 35.24
He-P 4035.08	10 CFR 35.21, 35.24
He-P 4035.09	10 CFR 35.22, 35.24
He-P 4035.10	10 CFR 35.24
He-P 4035.11	10 CFR 35.25, 35.27
He-P 4035.12	10 CFR 35.29, 35.80
He-P 4035.13	10 CFR 35.32
He-P 4035.14	10 CFR 35.33, 35.3045
He-P 4035.15	10 CFR 35.49
He-P 4035.16	10 CFR 35.50, 35.60
He-P 4035.17	10 CFR 35.50, 35.60
He-P 4035.18	10 CFR 35.51, 35.61
He-P 4035.19	10 CFR 35.53, 35.63
He-P 4035.20	10 CFR 35.57, 35.65
He-P 4035.21	10 CFR 35.59, 35.67
He-P 4035.22	10 CFR 35.60, 35.69
He-P 4035.23	10 CFR 35.61, 35.69
He-P 4035.24	10 CFR 35.70
He-P 4035.25	10 CFR 35.75
He-P 4035.26	10 CFR 35.80, 35.647
He-P 4035.27	10 CFR 35.90, 35.209
He-P 4035.28	10 CFR 35.92
He-P 4035.29	10 CFR 35.100
He-P 4035.30	10 CFR 35.120
He-P 4035.31	10 CFR 35.200
He-P 4035.32	10 CFR 35.204
He-P 4035.33	10 CFR 35.205
He-P 4035.34	10 CFR 35.220
He-P 4035.35	10 CFR 35.300
He-P 4035.36	10 CFR 35.310
He-P 4035.37	10 CFR 35.320
He-P 4035.38	10 CFR 35.320
He-P 4035.39	10 CFR 35.500
He-P 4035.40	10 CFR 35.520

He-P 4035.41	10 CFR 35.400
He-P 4035.42	10 CFR 35.410
He-P 4035.43	10 CFR 35.415
He-P 4035.44	10 CFR 35.406
He-P 4035.45	10 CFR 35.404
He-P 4035.46	10 CFR 35.420
He-P 4035.47	10 CFR 35.600
He-P 4035.48	10 CFR 35.605
He-P 4035.49	10 CFR 35.606
He-P 4035.50	10 CFR 35.610
He-P 4035.51	10 CFR 35.615
He-P 4035.52	10 CFR 35.620